

STATE OF VERMONT
BOARD OF MEDICAL PRACTICE

In re: Herbert Jack Breite, M.D.

Docket No. MPC 32-0303

MOTION FOR SUMMARY SUSPENSION

NOW COMES Petitioner, the State of Vermont, by and through Attorney General William H. Sorrell and undersigned counsel, Assistant Attorney General, James S. Arisman, and alleges as follows:

1. Herbert Jack Breite, M.D. (Respondent) holds Vermont Medical License Number 042-0005403, issued on November 19, 1974.
2. Jurisdiction vests with the Vermont Board of Medical Practice (Board) by virtue of 26 V.S.A. §§ 1353, 1354, & 1398 and 3 V.S.A. § 814(c).

I. Background.

3. A complaint against Respondent Breite was opened by the Vermont Board of Medical Practice on March 12, 2003 subsequent to receipt of information from James Rawson, an investigator for the internet clearinghouse of the Federation of State Medical Boards.¹ The Federation's internet clearinghouse investigates internet prescribing by physicians and disseminates information to state medical boards regarding the conduct of individual practitioners and general problems and risks related to internet prescribing.

1. The Federation of State Medical Boards, the umbrella organization representing the state medical boards of the United States, its territories, the District of Columbia, Puerto Rico, and 13 state boards of osteopathic medicine, provides leadership and services to medical boards charged with regulating the field of medicine and protecting the quality, safety, and integrity of health care through the promotion of high standards for physician licensure and practice.

4. On or about March 4, 2003 investigator Rawson placed an internet order for 3 Viagra 100 mg tablets with NumberOneRx.com². NumberOneRx provides the following information to the public regarding its business activities: "Medications prescribed online and shipped overnight to your door". The domain name, NumberOneRx.com is registered to Ayayai.com, P.O. Box 0832-1270, Panama City, Panama.

5. Investigator Rawson provided information in his request for a Viagra prescription that included the following: d.o.b.: 7/7/77; sex: male; height: 5'8"; weight: 160 lbs; and body mass index: 24. Rawson also stated that he consumed one or two beers per day and smoked cigars daily. Rawson offered only the following as his reason for ordering Viagra:

"I Need To Perform Better In Bed" and "I Feel Like I Can Better Preform [sic] With Viagra".

Personal and medical information was provided by investigator Rawson by filling in blanks in response to questions on the NumberOneRx "Medical Questionnaire/Order Request" form, which appears on the company's website. See Exhibit 1 (attached hereunto). Rawson denied any of the complicating factors included within the questionnaire.

6. Investigator Rawson filled out blanks on the NumberOneRx "Medical Questionnaire/Order Request" form to provide his street address, E-Mail address, and telephone numbers. Rawson indicated that he had read, understood, and agreed with the company's required "Customer Responsibility Statement" (attached hereunto as Exhibit 2) and "Informed Consent" (attached hereunto as Exhibit 3). The Customer Responsibility Statement included the following language that the customer was to affirm, "I will contact the

2. Currently d/b/a: NumberOneRx.net .

prescribing physician and pharmacy immediately upon any complications, issues, or questions regarding the requested medication(s).”

7. On or about March 4, 2003 Investigator Rawson completed the NumberOneRx on-line form, ordered three 100 mg Viagra tablets, and paid \$97.00 by credit card and \$18.00 for shipping and next day delivery. See Affidavit of James Rawson (attached hereunto as Exhibit 4).

8. The name of Respondent, Herbert Jack Breite, M.D., appeared nowhere within the contents of the NumberOneRx website. Nor did the website include any information as to how to contact Respondent Breite or any other prescribing physician.

II. Respondent's Prescribing for James Rawson.

A. Viagra: PDR Information.

9. Viagra (sildenafil citrate) is used to treat male erectile dysfunction. Viagra works with sexual stimulation to help achieve erection. Viagra presents a number of possible risks for male users. See Physician's Desk Reference (57th ed., 2003) at 2653-2656. Possible side effects include angina, headache, flushing, diarrhea, and dizziness. Other undesirable possible side effects include painful urination, vision problems, chest pain, fainting, foot/ankle swelling, or painful/ prolonged erections (lasting more than four hours). Viagra is contraindicated for patients using organic nitrates, either regularly and/or intermittently, in any form. Prior to prescribing Viagra, according to the PDR, physicians should carefully consider whether vasodilatory effects, particularly in combination with sexual activity, could adversely affect patients with underlying cardiovascular disease. Viagra may interact with a number of medications, including nitrate medications, nitroprusside, erythromycin, antifungals, high

blood pressure medicines, and certain HIV protease inhibitors. Viagra is contraindicated for patients with a number of conditions including certain allergies, penis conditions such as fibrosis or priapism³, sickle cell anemia, blood system cancers, kidney or liver disease, bleeding disorders, ulcers, heart disease, stroke, and high or low blood pressure.

10. The evaluation of erectile dysfunction by a physician should include a determination of potential underlying causes and the identification of appropriate treatment following a complete medical assessment. While Viagra reportedly has been beneficial to many males with properly diagnosed erectile dysfunction, it also presents substantial risks to users. Physicians should discuss with patients possible adverse symptoms, and patients should be counseled to refrain from further sexual activity in such circumstances and to discuss the episode with their physician.

B. Improper Care and Prescribing.

11. Investigator Rawson received by E-Mail a notice that his order had been received and another notice indicating that his order had been shipped. Neither notice included any reference to Respondent Breite or the name of any other physician.

12. On or about March 6, 2003 Investigator received by FedEx delivery a package containing a pill vial with three 100 mg Viagra tablets inside. The pill vial bore a label with Rawson's name typed on it. The label indicated that the prescription had been filled by Prescription Resources of Charlotte, North Carolina. The label also bore the name of "Dr. Herbert Jack Breite". However, neither the label nor any other enclosed information (i.e.,

3. If priapism is not treated immediately, penile tissue damage and permanent loss of potency could result.

printed general information regarding Viagra) included any indication as to the physician's office address, telephone number, E-Mail address, specialty, or state(s) of licensure. See Exhibit 5 (attached hereunto).

13. Investigator Rawson never provided any information to Respondent Breite other than that included in the content of the NumberOneRx "Medical Questionnaire/Order Request" form. See Exhibit 1. Investigator Rawson has never met Respondent Breite or been examined by him. Respondent Breite has never taken a medical history from investigator Rawson or received copies of Rawson's prior medical records. Respondent Breite has never spoken with investigator Rawson, written to him, or E-Mailed him. Respondent has never communicated with any practitioner who has previously treated Rawson, to the best of the investigator's knowledge. Respondent has never provided Rawson with his telephone number, address, E-Mail address, or offered that Rawson could contact him regarding questions, concerns, side effects, or medical problems.

14. Here, in sum, Respondent prescribed a potentially dangerous drug with known risks and adverse side effects to investigator Rawson, with only the most minimal information available to him regarding Rawson's medical history and physical condition. Respondent took no action to obtain additional information from Rawson, to counsel him regarding the drug, or to make himself available to the patient to answer questions or respond to complications that might develop. Respondent never saw Rawson or conducted a physical examination of him. Respondent never met, spoke with, or communicated in any way with Rawson.

15. Because he failed to examine investigator Rawson Respondent could not and did not personally attempt to determine whether Rawson had specific medical problems and to determine a specific diagnosis.

16. Because he failed to communicate directly with investigator Rawson, Respondent could not and did not personally attempt to establish a reliable medical history or determine whether Rawson had provided accurate information regarding himself and his medical condition.

17. Because he failed to communicate with investigator Rawson, Respondent could not and did not personally provide information to him and answer questions regarding the likely benefits and possible risks of the prescribed medication. Nor did Respondent review and clarify through discussion Rawson's needs and expectations as to the drug, Viagra.

18. Because he failed to communicate with investigator Rawson, Respondent could not and did not provide any follow-up to Rawson to assess the therapeutic outcome and any further medical needs that Rawson might have required.

19. For a valid physician-patient relationship to exist there must be a contract express or implied, between the doctor and the patient. Prior to receipt of the three Viagra tablets Investigator Rawson had no knowledge of Respondent Breite's existence and no collaborative relationship with the Respondent. Here, the physician-patient relationship was established when Respondent undertook diagnosis, treatment, and prescribing for investigator Rawson. Thus, Respondent assumed the obligations, responsibilities, and patient rights associated with establishing and maintaining an appropriate physician-patient relationship.

C. American Medical Association Standards.

20. The American Medical Association (AMA) takes the position that a physician who offers prescriptions solely on the basis of an online questionnaire, without having examined the patient, has provided care “well below” the minimum standard of care. See American Medical Association, Report of the Board of Trustees 35-1-99, Internet Prescribing. The AMA holds that internet prescribing of Viagra is “dangerous and highly inappropriate” when it occurs without examination of the patient, without dialogue with the patient regarding treatment alternatives and the planned course of treatment, without an attempt to establish a reliable medical history, with no provision by the physician of information about the benefits and risks of the drug, and no follow-up with the patient. *Id.*

21. The AMA provided further guidance to physicians regarding internet prescribing in 2002:

[T]here are a number of Internet Web sites that prescribe and dispense prescription medications (e.g., Viagra and Cipro) based solely on an online questionnaire, with no other interaction between the physician and patient. A number of national organizations, including the AMA and the Federation Of State Medical Boards (FSMB), as well as regulatory (e.g., Food and Drug Administration) and law enforcement (e.g., National Association of Attorneys General) bodies believe this constitutes substandard medical care and is a threat to the public health. If physicians are participating in these web sites, they are failing to meet minimum standards of medical care and may be subject to disciplinary actions.

See American Medical Association, Report of the Board of Trustees 6-A-02, Guidance for Physicians on Internet Prescribing.⁴

4. See also Code of Medical Ethics, American Medical Association (2000-2001 ed.) at § 8.06 (patients entitled to freedom of choice as to who will fill prescriptions and as to choice of physician); and § 8.08 (physician has ethical obligation to help patient make choices from among therapeutic alternatives consistent with good medical practice).

D. Respondent's Answer to Complaint.

22. On or about March 12, 2003 the Board of Medical Practice informed Respondent that a complaint regarding his internet prescribing had been opened. The Board received a letter dated March 21, 2003 from Respondent's attorney that provided no substantive response to the complaint and offered only a general denial that his client had violated any federal or state laws. By letter dated March 26, 2003 Board of Medical Practice investigator Philip J. Ciotti replied to the attorney and requested specific information regarding Respondent Breite's practice location and practice activities. Ciotti also requested copies of Respondent's contract with NumberOneRx. Ciotti provided a release signed by James Rawson and requested Rawson's medical records. Finally, Ciotti requested information as to Respondent's prescribing activities during the past two years. See Affidavit of Philip J. Ciotti (attached hereunto as Exhibit 6).

23. The Board received a reply letter dated April 17, 2003 from Respondent's attorney that stated that Dr. Breite was "retired" but "has been involved in internet activity". The letter claimed that Respondent had no written contract with any internet pharmacy or service. The letter offered the following response to the Board's complaint:

With regard to my client's medical practice as a licensed Pennsylvania physician, some of his activities involve reviewing and evaluating requests for initial or refill prescriptions via internet applications. These requests are either approved as appropriate or denied as inappropriate. The strictest of medical standards and scrutiny are applied to these requests which are individually reviewed by Dr. Breite in order to avoid drug interaction or abuse. The submitted patient clinical history which accompanies each and every request serves as the basis for approval or denial.

The attorney's response also asserted, "While there are public records evincing the fact that my client did at some time possess a valid Vermont medical license, there is nothing to

indicate anything further. Possessing a license to practice and actually practicing are by far not the same matter.” A fair characterization of this letter’s content is that it is conclusory, self-contradictory, and non-responsive. Finally, the letter failed to provide investigator Rawson’s medical records as had been requested by the Board, with a properly signed release.

E. Respondent’s Vermont License Status and Renewal Applications.

24. Respondent holds a current, active Vermont medical license. See Exhibit 7, (attached hereunto). Respondent’s 2002 renewal application described his practice setting as “RETIRED” and checked an answer indicating that he was “Not currently in active practice”. In 2000 Respondent’s renewal application answered “n/a” to the request for his office address. Respondent’s 1998 renewal application described him as not in active practice.

III. State’s Motion.

25. The conduct described in paragraphs 11 through 19 (internet prescribing, failure to examine patient, failure to take appropriate medical history, failure to document care of patient, and failure to communicate with patient) constitutes a “gross failure to use and exercise on a particular occasion or the failure to use and exercise on repeated occasions, that degree of care, skill and proficiency which is commonly exercised by the ordinary skillful, careful and prudent physician engaged in similar practice under the same or similar conditions, whether or not actual injury to a patient has occurred.” 26 V.S.A. § 1354(a)(22). Such conduct also constitutes a “failure to practice competently” by “performance of unsafe or unacceptable patient care” or “failure to conform to the essential standards of acceptable and prevailing practice”. 26 V.S.A. § 1354(b).

26. Respondent's conduct, as described in paragraphs 11 through 19, also constitutes abandonment of a patient, 26 V.S.A. § 1354(a)(4); and evidence of unfitness to practice medicine, 26 V.S.A. § 1354(a)(4). Respondent's conduct, as described in paragraphs 11 through 19, also may constitute evidence of the practitioner allowing his name or license to be used by a person, group, or corporation when not actually in charge of or responsible for the treatment given.

27. The conduct described in paragraph 23 (failure to promptly provide patient records upon proper request) constitutes further unprofessional conduct by Respondent. 26 V.S.A. § 1354(a)(10).

28. The conduct described in paragraph 24 (false answer on renewal application) constitutes further unprofessional conduct by Respondent in that it constitutes fraudulent procuring or use of a license. 26 V.S.A. § 1354(a)(1).

29. The above specified conduct constitutes unprofessional conduct "whether or not the conduct at issue was committed within or without the state" of Vermont. 26 V.S.A. § 1354(a). Further, such conduct also constitutes unprofessional or dishonorable conduct, pursuant to 26 V.S.A. § 1398.

30. Respondent's unprofessional conduct, while a holder of a Vermont medical license, is egregious and endangers the public health, safety, or welfare of residents of the State of Vermont and elsewhere. Such conduct imperatively requires summary suspension of Respondent's Vermont license to practice medicine as emergency action to protect the public health, safety, or welfare, pending further proceedings or order of the Board. 3 V.S.A. § 814(c).

31. The continuing ability of Respondent to present a Vermont medical license, as purported proof that he is deemed qualified by this State to practice medicine represents a danger to the public health, safety, and welfare and is contrary to the Board's responsibility for protection of the public and regulation of the medical profession. See Perry v. Vermont Medical Practice Board, 169 Vt. 399, 403-05 (1999) (protection of society through regulation of medical profession is compelling State interest and may include exclusion from practice of practitioners by suspension or revocation). Here, summary suspension is imperatively required so as to immediately protect the members of the public, whether in Vermont or elsewhere. Perry v. Board of Medical Practice at 405 (interstate component of licensing function is integral to regulatory responsibilities of Board of Medical Practice).

WHEREFORE, petitioner, the State of Vermont, respectfully moves the Board of Medical Practice for SUMMARY SUSPENSION of the license of Respondent Herbert Jack Breite, M.D., to practice medicine in the State of Vermont, and moves the Board for entry of an express finding that protection of the public health, safety, and welfare imperatively requires such action, pursuant to 3 V.S.A. § 814(c), pending further proceedings or action of the Board.

Dated at Montpelier, Vermont this 2nd day of June 2003.

STATE OF VERMONT

WILLIAM H. SORRELL
ATTORNEY GENERAL

by:


JAMES S. ARISMAN
Assistant Attorney General

Office of the
ATTORNEY
GENERAL
109 State Street
Montpelier, VT
05609

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